



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/758,415

01/16/2004

William S. Brusilow

2930-109

5654

6449

7590

11/06/2007

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

VAKILI, ZOHREH

ART UNIT

PAPER NUMBER

1614

NOTIFICATION DATE

DELIVERY MODE

11/06/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/758,415	Applicant(s) BRUSILOW, WILLIAM S.	
	Examiner Zohreh Vakili	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 and 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37.CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1/16/2004, 3/16/2004, 12/20/2004, 01/18/2005.

DETAILED ACTION

Claims 1-20 are presented for examination.

Applicant's election of Group I drawn to a method for treating a polyglutamine disease in the reply filed on August 9, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6-9 and 12-20 are withdrawn from consideration as being directed to non-elected subject matter. Claims 1-5 and 10-11 read on the elected invention and are herein examined on the merits.

Applicant's submission of Information Disclosure Statement (IDS) filed 01/16/2004, 03/16/2004, 12/02/2004, and 01/18/2005 has been received and entered into present the present application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Apostolakis et al., Brain Research Bulletin, or Ginefri-Gayet et al., Pharmacology Biochemistry and Behavior.

Apostolakis teaches methionine sulfoximine (MSO) is a centrally acting neurotoxin with convulsive properties; it has been used in study of epilepsy. MSO suppresses the formation of glutamine (see page 257, col. 1, first paragraph). Apostolakis further teaches pharmaceutical unit doses in an amount of methionine sulfoxime of 2 mg/ml normal saline and 200 micro gram/100 micro liter administered intravenously (IV) and intracerebroventricularly (IVT). The animals were sacrificed at different times after MSO administration (see page 257, column 2).

Ginefri-Gayet teaches pharmaceutical unit doses in an amount of methionine sulfoxime of 50-75 micro gram/10 micro liters. See page 174, column 2, under ICV Injection of MSO.

Consequently, the reference anticipates the claimed invention defined in claims 1-5.

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Liedtke et al. (US Pub. No. 20030013650 A1).

Liedtke teaches that the present invention relates to the identification in vertebrate animals including humans, of an ion channel for rapid conduction of cations, among them, Ca^{2+} . This ion channel, named VR-OAC, demonstrates activity as an osmoreceptor, and also demonstrates a role in mechanical stimulation and responsiveness (see page 1, paragraph 2). VR-OAC is expressed in nerve-cells of the

Art Unit: 1614

hippocampus, CA1 region, a region of importance for memory and in epileptic seizures (page 6, paragraph 89). Liedtke further teaches that the recombinant protein can be refolded prior to or after cleavage to form a functionally active polypeptide. Suitable redox (reducing/oxidizing) agent pairs include, but are not limited to, reduced glutathione/glutathione disulfide, cystine/cysteine, cystamine/cysteamine (see page 16, paragraph 203). Mammalian expression vectors contemplated for use in the invention include vectors with inducible promoters, such as, a glutamine synthetase/methionine sulfoximine co-amplification vector, (see page 16, paragraph 207).

Consequently, the reference anticipates the claimed invention defined in claims 10 and 11.

Conclusion

No claims of the present application are allowed.

Any inquiry concerning this communication should be directed to Zohreh Vakili, telephone number 571-272-3099. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m., Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

Art Unit: 1614

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili
Patent Examiner
Art Unit 1614

October 12, 2007

 10/15/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER